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ACTION	*DATE*	*INITIAL*
Adopted	3/26/07	
Reviewed	1/7/11	MAS
Reviewed	1/10/12	MAS
Reviewed	1/14/14	MAS
Reviewed		
Revised	1/5/15	MAS

Changes made: Testing personnel defined
Replaces: 7/21/10

TITLE: **COAGUCHEK XS SYSTEM**

PRINCIPLE

The CoaguChek XS PT Test, used as directed with the CoaguChek XS Meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood works with the chemicals in the test strip to make a small electric current in the test strip that measures blood-clotting time.

PURPOSE

The CoaguChek XS System is intended for use by professional heathcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The CoaguChek Xs System uses fresh capillary or non-anticoagulated venous whole blood.

POLICY

1. The CoaguChek XS will be used by the nursing staff of the Internal Medicine Anti-Coagulation Clinics of the Rivercampus CentraCare Clinic, Health Plaza and CentraCare Clinic Lab – Little Falls.
2. To be certified in the procedure and, therefore, be considered a valid operator, staff will go through initial training with a designated trainer (a Roche Diagnostics representative and/or the Point of Care Specialist/Team Lead). This will consist of hands-on training and completing the validation checklist. To remain a valid operator, competency will be assessed with 6 mos split sample testing and review of procedure on an annual basis. The Point of Care Team Lead and/or Technical Specialist will also monitor operator performance on a continuous basis with the data management system. If an operator appears to do a very low volume of testing, and the unit director deems it necessary for them to remain a valid operator, that operator will be required to repeat hands-on training.

STANDARD OF CARE

Patient can expect:

1. Timely performance of the whole blood PT tests.
2. To be instructed about the procedure to be performed.
3. All persons doing whole blood PT testing will have proper training and annual Recertification.

STANDARD OF PRACTICE

The employee doing whole blood PT testing will be certified in the use of the meter, including the test procedure. The employee doing the testing will report the results to the patient's Dr. Communication will be via computer entry unless the INR is >8.0. The nurse will use the test results to give the prescribed treatment for monitoring anitcoagulation therapy. Prescribed treatment is per protocol, which is reviewed by the anit-coag medical director yearly.

EQUIPMENT AND SUPPLIES

- CoaguChek XS Meter
- CoaguChek XS PT Test Strip
- Test Strip Code Chip
- Lancet

REAGENT STORAGE REQUIREMENTS

- Store the test strips in their container, with the cap closed.
- Test Strips can be stored at room temperature or in the refrigerator (2 to 30^{o} C or 36 to 86^{o}C).
- When stored properly, the test strips can be used up until the expiration date printed on the test strip container.
- You must use the test strip within **10 minutes** of removing it from the container.

QUALITY CONTROL

The CoaguChek XS System has quality control functions integrated into the meter and test strips, so you never have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test.

When the quality control test runs, the letters **QC** flash on the meter's display. When the quality control test completes, a checkmark appears following the letters **QC.** Then the meter continues to run the blood test.

If the quality control test fails, the meter displays an error message for the QC. See the Error Messages section of the user manual for an explanation of this error and what to do when it occurs.

Call Roche Diagnostics Technical Service Center at 1-800-428-4674 if unacceptable results persist.

HOW THE SYSTEM WORKS

The CoaguChek XS System includes a meter and CoaguChek XS Pt test strips. Each box of test strips has its own code chip that you insert into the meter. The code chip contains important information about the test strips such as their expiration date and lot number. The meter and test strips wok together to provide a safe and reliable system for testing blood clotting time.

The CoaguChek XS System makes measuring blood clotting time easy. The display on the meter guides you through the testing process. With the code chip inserted in the meter, you simply insert a test strip and apply a blood sample. The meter displays the result memory so that you can easily recall results.

The CoaguChek XS PT test strip contains various ingredients. When a blood drop is applied, the meter starts the test and the blood mixes with the ingredients on the test strip. When the meter determines that the blood has clotted, it stops the measurement and calculates the result.

CLEANING THE METER

It is important to keep the meter clean. Clean the meter whenever it looks dirty or, if a regular schedule is preferred, clean the meter each time you open a new box of test strips.

Ensure that the swab or cloth is only damp, not wet!

Cleaning/Disinfecting the Meter Housing:

Use only the following items for cleaning/disinfecting the CoaguChek XS meter housing for a contact time of > 1 minute:

- 70% isopropyl alcohol
- 10% Sodium hypochlorite (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)
- NOTE: Do not use any other disinfectants/cleaning solutions on the meter housing

1. Clean/Disinfect the exterior, with the meter powered off; wipe the meter's exterior clean. Do not let liquid accumulate near any openings. Make sure that no liquid enters the meter.
2. Dry the exterior, with a lint-free tissue, dry the meter. Wipe away residual moisture and fluids after cleaning the housing. Allow wiped areas to dry for at least 10 minutes before performing a test.

Cleaning/Disinfecting the Test Strip Guide:

Use only 70% isopropyl alcohol or 10% bleach solution to clean/disinfect the CoaguChek XS test strip guide. Do not use any other cleaning /disinfecting solutions on the test strip guide. Use of other solutions could result in damage to the meter.

1. With the meter powered off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter, then rinse the cover with water or wipe it clean.

2. Clean/disinfect the test strip guide.

    a. Hold the meter upright with the test strip guide facing down. See images below.
    b. Clean the easily accessible areas with a cotton swab
    c. Ensure the swab is only damp, not wet
    d. Apply cleaning agent for a contact time of >1 minutes
    e. Wipe away residual moisture and fluids.

3. With the cover off, allow the test strip guide to dry for about 10 minutes.
4. Close the cover, and make sure it snaps into place.

Correct meter position during cleaning process:

CORRECT WAY

INCORRECT WAY

New firmware provides an additional fail-safe to prevent cleaning related malfunctions. In the event of a temperature irregularity, an **error 9** message is displayed prior to blood application. An **error 9** message prevents further testing.

There is no risk to patient results as all CoaguChek XS metes with SilGel coated heaters are further protected by the new firmware fail-safe feature (**error 9**) which checks fro temperature irregularities during the heating phase of the meters. Any temperature irregularity will cause the meter to display **error 9**, preventing further testing.

If you receive an **error 9**, contact Roche Diagnostics Point of Care Technical Services at 1-200-428-4674.

PROCEDURE FOR PATIENT TEST

1. Gather Items needed, such as the meter, test strips, test strip code chip, and Lancets.
2. Make sure the code number on the test strip container and the code chip match.
3. Make sure the meter is turned **off.** With the code number facing up, insert the code chip into the code chip slot until it snaps into place.
4. Have the patient wash his/her hands in warm, soapy water, or clean the fingertip with an alcohol wipe. (Fingertip should be thoroughly dry before testing).
5. Take a test strip out of the container. ***You have 10 minutes to use a test strip once you remove it from the container.***
6. Slide the test strip into the test strip guide in the direction of the arrows until it stops. The meter will turn itself on.
7. Confirm that the number displayed matches the number on the test strip container then press **M.**
8. After about a 30-second warm-up a flashing test strip appears and the meter begins a countdown. ***You have 180 seconds to apply blood to the test strip***.
9. Perform a fingerstick puncture and gently squeeze from the base of the finger to develop a hanging drop of blood.
10. Dose the target area of the strip by either bringing the patient's finger to the top of the test strip or by bringing the meter to the patient's finger so that the side of the tests strip touches the blood drop.
11. Within 15 seconds of sticking the fingertip, apply the blood to the target areas of the test strip. Hold the blood drop to the test strip until you hear a beep. The flashing blood drop symbol disappears.
12. The result will appears in about 1 minute.
13. Record the result.
14. Place the used test strip and lancet in an approved container.
15. Turn off the meter.

See the User Manual for Optional Testing Methods using capillary tubes or venous blood samples.

REPORTING RESULTS

There are two recommended therapeutic ranges: a less intense range of 2.0-3.0 INR and a more intense range of 2.5-3.5 INR for patients with mechanical heart valves. The physician determines the appropriate therapeutic range.

LINEARITY

The CoaguChek XS PT test strips provide test results if the INR value is between 0.8 and 8.0. If the meter displays <0.8, >8.0 or the Error Message 7, repeat the test with a new strip. If the results persist, the result must be checked using another method.

LIMITATIONS OF THE METHOD

- The CoaguChek XS PT test uses only fresh capillary or non-anticoagulated venous whole blood. *Plasma or serum cannot be used.*
- Use only plastic syringes without anticoagulants or additives. *Glass tubes or syringes must not be used.*
- The blood drop must be a minimum of **10 ul** in volume.
- Never add more blood to test strip after test has begun or perform another test using the same fingerstick.
- Hematocrit ranges between 25-55% do not significantly affect test results.
- The presence of anti-phospholipid antibodies such as Lupus antibodies can potentially lead to prolonged clotting times, i.e., elevated INR values.
- No interference with *in vitro* spiked samples, bilirubin up to 30 mg/dl, lipemic samples containing up to 500 mg/dl of triglycerides, hemolysis up to 1000 mg/dl, or heparin concentrations up to 0.8 U/ml.
- **Never** store the meter in damp or humid conditions (greater than 85% humidity).
- **Always** operate the meter at temperatures between 65^{o}F and 90^{o}F (18^{o}C and 32^{o}C).

SEE THE COAGUCHEK XS SYSTEM USER MANUAL AND PACKAGE INSERTS FOR COMPLETE AND UP-TO-DATE PRODUCT SPECIFICATIONS AND LIMITATIONS.

REFERENCES

1. CoaguChek XS System User Manual.
2. CoaguChek XS System professional training DVD
3. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Technical Procedure Manuals – Second Edition (GP2-A2). Villanove, PA: National Committee for Clinical Laboratory Standards, 1992.